BOX PCT

ATTORNEY'S DOCKET NO: 23739

U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE		DATE: 19 April 2000 (19.04.2000)
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLN. NO. (if known): Not Yet Assigned 09/529734
INTERNATIONAL APPLICATION NO.: PCT/US98/22372	INTERNATIONAL FILING DATE: 23 October 1998 (23.10.98)	PRIORITY DATE CLAIMED: 23 October 1997 (23.10.97)

TITLE OF INVENTION: **THE USE OF AN AQUEOUS SOLUTION IN THE PREPARATION OF A MEDICAMENT FOR USE IN THE TREATMENT OF LIVE ANIMALS**

APPLICANT(S) FOR DO/EO/US: HINZE, Gilbert Theo

Applicant hereby submits to the Unites States Designated/Elected Office (DO/EO/US) the following items and other information:

1. x This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.

2. __ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.

3. x This express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the time limit set in 35 USC 371(b) and PCT Articles 22 and 39(1).

4. X A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. x A copy of the International Application as filed (35 U.S.C. 371(c)(2)):

   a. X is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ____ has been transmitted by the International Bureau.
   c. ____ is not required, as the application was filed in the United States Receiving Office (RO/US)

6. __ A translation of the International Application into English (35 U.S.C. 371(c)(2)).

7. __ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))

   a. __ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. __ have been transmitted by the International Bureau.
   c. __ have not been made; however, the time limit for making such amendments has NOT expired.
   d. X have not been made and will not be made.

8. __ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. __ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).

10. __ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

ITEMS 11. TO 16. BELOW CONCERN OTHER DOCUMENT(S) OR INFORMATION INCLUDED:

11. __ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

12. __ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. __ A **FIRST** preliminary amendment.
    __ A **SECOND** or **SUBSEQUENT** preliminary amendment

14. __ A substitute specification.

15. __ A change of power of attorney and/or address letter.

16. __ TRANSMITTAL FORM; FEE CALCULATION; INTERNATIONAL PUBLICATION WO 99/20287; INTERNATIONAL PUBLICATION DATE 29 APRIL 1999; APPLICATION CONSISTING OF 11 PAGES INCLUDING; 8 PAGES TEXTUAL SPECIFICATION, 2 PAGES OF 8 CLAIMS; 1 COVER SHEET CONTAINING THE ABSTRACT; 0 SHEETS DRAWINGS PCT/IPEA/416 NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT; PCT/IPEA/409 INTERNATIONAL PRELIMINARY EXAMINATION REPORT WITH 4 ANNEXED SHEETS OF CLAIMS AND DRAWINGS TO BE EXAMINED; PCT/ISA/210 INTERNATIONAL SEARCH REPORT;

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U.S. APPLICATION NO. (if known) 09/529734	INTERNATIONAL APPLICATION NO. PCT/US98/22372	DATE: 19 April 2000 (19.04.2000)

17. x The following fees are submitted:	CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492(a)(1)-(5): Search Report has been prepared by the EPO or JPO:.....$840.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482).....$670.00	$ 670.00	
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)).....$760.00		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....$970.00		
International preliminary examination fee (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4).....$ 96.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	**$ 670.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than ___ 20 ___ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

CLAIMS	NO. FILED	NO. EXTRA	RATE		
TOTAL	8 -20=	0	X $ 18.00	$	**0.00**
INDEPENDENT	3 - 3=	0	X $ 78.00	$	0.00
Multiple dependent claims(s) (if applicable)			+ $260.00	$	0.00
TOTAL OF ABOVE CALCULATIONS =				$	**670.00**
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				$	**0.00**
SUBTOTAL =				$	670.00
Processing fee of **$130.00** for furnishing the English translation later than ___ 20 ___ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$	0.00
TOTAL NATIONAL FEE =				$	670.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00 per property +**				$	**0.00**
TOTAL FEES ENCLOSED =				$	**670.00**
				Amount to be: refunded	$
				charged	$

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U.S. APPLICATION NO. (if known) 09/529734	INTERNATIONAL APPLICATION NO. PCT/US98/22372	DATE: 19 April 2000 (19.04.2000)

a. X One check in the amount of $670.00 to cover the above fees ,is enclosed.

b. __ Please charge my Deposit Account No. 14-0112 in the amount of $_____ to cover the above fees. (A duplicate copy of this sheet is enclosed.)

c. X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0112.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed to request that the application be restored to pending status.

Send All Correspondence To:

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Registration Number 26,965

Rev. 02/98

PCT/US98/22372

Applicant: Gilbert Theo HINZE Atty Docket No. 23739

Serial No._____ Filed: April 19, 2000

For: **THE USE OF AN AQUEOUS SOLUTION IN THE PREPARATION OF A MEDICAMENT FOR USE IN THE TREATMENT OF LIVE ANIMALS**

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(F) AND 1.27(C) - SMALL BUSINESS CONCERN

I hereby declare that I am:

( ) the owner of the small business concern identified below

( ) an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: **RADICAL WATERS IP (PTY) LTD**

ADDRESS OF CONCERN: Castleview South, 500 Tsitsa Street, Erasmuskloof, 0048, REPUBLIC OF SOUTH AFRICA

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-tim, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled **THE USE OF AN AQUEOUS SOLUTION IN THE PREPARATION OF A MEDICAMENT FOR USE IN THE TREATMENT OF LIVE ANIMALS** by inventor(s) Gilbert Theo HINZE described in

( ) the specification filed herewith

(x) Application Serial No. filed April 19, 2000

( ) Patent No. issued

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under

37 CFR 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.278)

Full Name_____

Address_____

_____

( ) Individual ( ) Small Business ( ) Nonprofit Organization

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(F) AND 1.27(C) - SMALL BUSINESS CONCERN

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Gilbert Theo Hunje.

Title of Person Signing Dr. No7 Summit Place

Address of Person Signing: 5th Stret Halfway Gardens Halfway House RSA.

Signature _____ Date 08/04/00.

THE USE OF AN AQUEOUS SOLUTION IN THE PREPARATION OF A MEDICAMENT FOR USE IN THE TREATMENT OF LIVE ANIMALS

Field of the Invention :

This invention relates to the use of an aqueous solution in the preparation of a medicament for use in the treatment of live animals.

Background to the Invention :

For the purposes of this specification, the term "animal" should be construed to include within its meaning sheep, cattle. goats, pigs, chickens, ostriches, reptiles and the like; the term "disease" should be construed to include within its meaning diarrhoea; the term pathogen should be construed to include within its meaning micro-organisms such as E-coli; and the term "medicament" should be construed to include within its meaning oral bactericides and bactericidal inhalants. The Applicant envisages that the invention will be applicable particularly, but not exclusively, in the preparation of a medicament for use in the treatment of pathogenic micro-organisms in weaner piglets and chicklets.

The presence of antibiotic residues in food products lead to allergic and anaphylactic reactions in humans. The development of resistant strains of micro-organisms makes anti-microbials ineffective.

Object of the Invention :

It is accordingly an object of the invention to provide inexpensive, novel and alternative anti-microbials that overcome the above disadvantages.

In accordance with a first aspect of the invention, there is provided the use of a composition in the preparation of a medicament for use in the treatment of pathogenic micro-organisms in a live animal, the composition comprising an electro-chemically activated anion-containing aqueous solution.

In accordance with a second aspect of the invention there is provided a composition in the preparation of a medicament for the treatment of pathogenic micro-organisms in live animals, the composition comprising an electro-chemically activated anion-containing aqueous solution, the composition substantially as herein defined.

In accordance with a third aspect of the invention there is provided a method of treating pathogenic micro-organisms in a live animal, the method including the step of administering a dosage of a composition comprising an electro-chemically activated anion-containing aqueous solution to the animal, the anion-containing aqueous solution being substantially as herein defined.

The anion-containing aqueous solution may be prepared by means of electrolysis of an aqueous solution of a salt. The salt may be sodium chloride. In particular, it may be non-iodated sodium chloride or potassium chloride.

The anion-containing solution and the associated cation-containing solution may be produced by an electro-chemical reactor or so-called electrolysis device.

The electro-chemical reactor may include a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between the electrodes so as to separate an annular inter electrode space into a catalytic and an analytic chamber.

The anion-containing solution is referred to hereinafter for brevity as the "anolyte solution" and the cation-containing solution is referred to hereinafter for brevity as the "catholyte solution".

The anolyte solution may be produced from an aqueous NaCl solution, electrolysed to produce radical cation and radical anion species, the anolyte solution having a redox potential up to about + 600 mV to + 800 mV. These species may be labile and after about 96 hours, the various radical species may disappear with no residues being produced.

The anolyte solution may have a pH of about 6,5 to 7,5. The anolyte solution may include species such as ClO; ClO^-; HClO; OH^-; HO_2^-; H_2O_2; O_3; $S_2O_8^{2-}$ and $Cl_2O_6^{2-}$.

These species have been found to have a synergistic anti-bacterial and/or anti-viral effect which is generally stronger than that of chemical bactericides and has been found to be particularly effective against viral organisms and spore and cyst forming bacteria.

The redox potential of the anolyte solution may be monitored during the process so that the treatment process may be monitored and controlled on a continuous basis.

The catholyte solution generally may have a pH of up to about 12-13 and a redox potential of about -980 mV. The catholyte solution may include species such as NaOH; KOH; $CA(OH)_2$; $Mg(OH)_2$; HO^- ; $H_3O_2^-$; HO_2^- ; $H_2O_2^-$; O_2^- ; OH^-; O_2^{2-} .

The method of treatment may include administering the anolyte solution by soaking, rinsing or dipping the animal in the anolyte solution, applying the anolyte solution as an inhalant via an atomising or fogging process or administering the anolyte solution orally. The soaking, rinsing or dipping process is suitable for animals which can be handled with relative ease.

The processes of atomising or fogging and oral administration by addition to drinking water are both suitable for animals such as weaner piglets and

chicklets which are susceptible to stress and accompanying weight loss. The atomising or fogging process may include the step of atomising the solution into the atmosphere in a volume to be treated, forming droplets of between 5 and 100 micrometre. The method may include the preliminary step of enclosing the volume to be treated prior to atomising or fogging the enclosed volume.

The atomising or fogging process is preferably conducted at pre-determined intervals so as to maintain a suitable level of anolyte concentration in the atmosphere, thus utilising the optimum microcidal and other properties of the anolyte solution in accordance with the required administration rate.

The anolyte solution may also be applied by an atomising process in air ducting systems to destroy air-borne micro-organisms and to destroy micro-organisms present in the airways and lung tissue by inhalation.

The treatment of the animal as described above may be conducted so as to improve the weight gain as a result of the anti-microbial action of the anolyte solution.

The oxidising-free radicals present in the anolyte solution may act synergistically at a bacterial cellular level.

The anolyte solution may have a specific anion concentration and distribution and a redox potential in accordance with the specific application.

The pathogenic micro-organisms to be treated may include enteric pathogenic micro-organisms and respiratory pathogenic micro-organisms.

Detailed Description of the Invention :

A preferred embodiment of the invention will now be described with reference to the accompanying experiments.

In a series of experiments, the bactericidal effect of the anolyte solution was tested on animals. The results are reflected in the tables below.

An electro-chemical reactor, including a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into a catalytic and an analytic chamber, was used to produce anolyte and catholyte solutions.

Experiment 1 - Weaner Piglets

The anolyte solution was added to the drinking water of the weaner piglets over a period of 14 days and the results were measured in terms of average

weight after the 14 day period. The average weight of the administered groups were compared with the average weight of the unadministered groups.

The administered groups showed relative weight gain relative to the unadministered groups. The relative weight gains of the administered groups are reflected in Table 1 below.

Experiment 2 - Broilers (Chicklets)

Day old broilers were administered with anolyte solution (10% diluted) by addition to drinking water for 7 days. (Group C3 - 12 000 chicklets). No antibiotic medication was administered during that time. Untreated control groups (C1, C2, C4 and C5 = total 48 000 chicklets) received normal drinking water during that time. The untreated groups were routinely medicated with Tylosin for 3 consecutive days.

Bacterial analyses of the drinking water of all groups were regularly conducted during the first 7 days. Other measurements included daily mortalities and morbidities throughout and pH and ORP determinations of the drinking water during the first 7 days. All results are reflected in Table 2 below.

Medication of drinking water with anolyte solution supplied to day-old

chicklets for the first period resulted in a significant reduction in mortalities throughout the growth and finishing period. Mortalities increased in all the groups from the 4th week onwards mainly due to respiratory disease. It is envisaged that these could be reduced by fogging the environment with anolyte solution to eliminate airborne respiratory pathogens by means of respiratory intake.

It has been found that the efficacy of the use of the anolyte solution in the treatment of live animals depends upon the concentration of the anions in the anolyte solution, as measured by the oxidation-reduction potential (ORP) or redox potential of the anolyte solution, the flow rate through the reactor, the exposure time, i.e. the contact time between the contaminated animal and the anolyte solution and the temperature during application. By measuring the redox potential of the anolyte solution during the treatment, for example, of a weaner piglet, the available free radical concentration can be monitored. Anolyte solution has been found to be more effective at lower than at higher temperatures.

It will be appreciated that many variations in detail are possible without departing from the scope and/or spirit of the invention as claimed in the claims hereinafter.

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TABLE 1

	Determinant	Trial Groups			
		R1TM	R2TF	R3CF	R4CM
Treatments	10% Anolyte in drinking water - days	13	13	0	0
	ORP range (mV)	600-650	600-650	100-150	100-150
	Replenishment (days)	2	2	-	-
Growth Performance	No per group	16	16	16	16
	(9/10/97) Day 0 x L Mass	8,24	6,08	7,66	6,01
	A D G	0,133	0,212	0,185	0,148
Treatment Courses Required	Diarrhea pig/group	(18%)	(12,5%)	(37,5%)	(100%)
	Respiratory symptoms pigs/group	(6,25%)	(12,5%)	(18,75%)	(100%)
	Cost of Treatment	R14,00	R14,00	R31,50	R126,00
	Cost of Treatment	R0,88	R0,88	R1,97	R7,41

EXCL. 3

AMENDED SHEET

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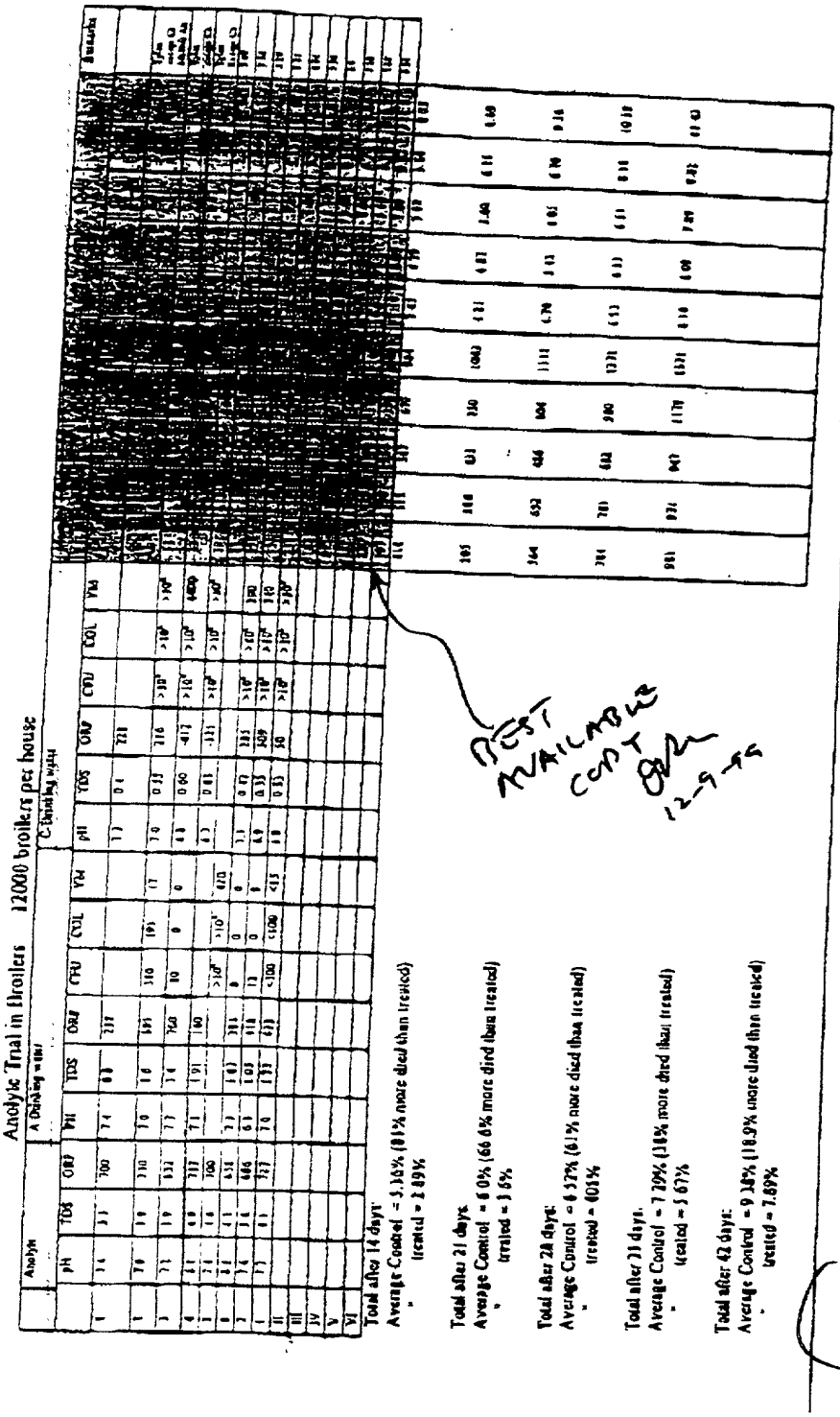
TABLE 2



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ENCL. 4

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AMENDED SHEET

Claims:

1. The use of a composition in the preparation of a medicament for use in the treatment of pathogenic micro-organisms in a live animal, the composition comprising an atomized electro-chemically activated, anion-containing aqueous solution.

2. A composition for the preparation of a medicament for the treatment of pathogenic micro-organisms in live animals, the composition comprising an atomized electro-chemically activated anion-containing aqueous solution.

3. A method of treating pathogenic micro-organisms in a live animal, the method comprising the step of fogging the animal with a dosage of a composition comprising an atomized electro-chemically activated anion-containing solution.

4. A composition as claimed in claim 2 wherein the anion-containing aqueous solution is prepared by means of electrolysis of an aqueous solution of a salt.

5. A composition as claimed in claim 4 wherein the anion-containing solution includes species selected from the group comprising: ClO; ClO^-; HClO; OH^-; HO_2^-; H_2O_2; O_3; $S_2O_8^{2-}$; and $Cl_2O_6^{2-}$.

6. A composition as claimed in claim 2 wherein the anion-containing solution is produced by an electro-chemical reactor, the electro-chemical reactor comprising a through flow, electro-chemical cell having two co-axial cylindrical electrodes with a co-axial diaphragm between the electrodes so as to separate an annular inter electrode space into a catalytic and an analytic chamber.

7. A composition as claimed in claim 2 wherein the anolyte solution has a redox potential of between +600mV and +800mV and a pH of between 6.5 and 7.5.

8. A method as claimed in claim 3 wherein the fogging process comprises the step of atomizing the solution into the atmosphere in a volume to be treated, forming droplets of between 5 and 100 micrometers.

DECLARATION FOR PATENT APPLICATION	Attorney Docket: 23739 Page 2 of 2

We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: Gilbert Theo HINZE

Inventor's Signature ______________________ Date 08/06/00

Residence: 119 Ostrich Road, Bromhof, Randburg 2194, ZA

Country of Citizenship: SOUTH AFRICA 2AX

Post Office Address: Same as residence

DECLARATION FOR PATENT APPLICATION	Attorney Docket: 23739 Page 1 of 2

As a below-named inventor(s), I/we hereby declare that:

My/Our residence(s), post office address(es) and citizenship(s) is/are as stated below next to my/our name(s).

I/We believe I/we am/are the original inventor, first and sole *(if only one name is listed below)* or the original, first and joint inventors *(if plural names are listed below)* of the subject matter which is claimed, and for which a patent is sought on the invention entitled:

THE USE OF AN AQUEOUS SOLUTION IN THE PREPARATION OF A MEDICAMENT FOR USE IN THE TREATMENT OF LIVE ANIMALS

the specification of which: (check one)

[ ] is attached hereto.

[X] was filed on 23 October 1998, as Serial No. PCT/US98/22372,

and was amended on 19 (if applicable).

We hereby state that we have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

We acknowledge the duty to disclose information which is material to the patentability of this application as defined by 37 CFR § 1.56.

We hereby claim foreign priority benefits under 35 U.S.C. § 119 of any foreign application(s) for patent or inventor's certificate listed below, and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Applications:

			Priority Claimed	
97/9486 (Application No.)	SOUTH AFRICA (Country)	23 /Oct. / 1997 (Day/Month/Year Filed)	[X] Yes	[ ] No
(Application No.)	(Country)	/ / (Day/Month/Year Filed)	[ ] Yes	[ ] No
(Application No.)	(Country)	/ / (Day/Month/Year Filed)	[ ] Yes	[ ] No

We hereby appoint Gary M. Nath, Reg. No. 26,965; Harold L. Novick, Reg. No. 26,011; Todd L. Juneau, Reg. No. 40,669; Lee C. Heiman, Reg. No. 41,827; Jerald L. Meyer, Reg. No. 41,194; Joshua B. Goldberg, Reg. No. 44,126; David Milligan, Reg. No. 42,893; David R. Murphy, Reg. No. 22,751; Paul A. Sacher, Reg. No. 43,418; Gregory B. Kang, Reg. No. 45,273; Charles D. Niebylski, Reg. No. P-46,116; and Deborah H. Yellin, P-45,904 as my attorneys to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith.

(12)

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Send Correspondence to:
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Washington, D.C. 20005 U.S.A.

We hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by 35 U.S.C. § 112, first paragraph, I/we acknowledge the duty to disclose material information as defined in 37 CFR § 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(U.S. Application Serial No.)	(U.S. Filing Date)	(Status--patented, pending, abandoned)
(U.S. Application Serial No.)	(U.S. Filing Date)	(Status--patented, pending, abandoned)